Billy Snipes, R.Ph.
Executive Vice President
Returns Online, Inc.
14108 Lochridge Industrial Blvd.
Covington, GA 30014
Phone: (770) 385-0070
Email: billys@returnsonline.com

Dockets and Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

July 12, 2002

Re: [Docket No. 02N-0204]
***Notice:* Bar Code Label Requirements for Human Drug Products; Notice of Public Meeting**

Returns Online, Inc. is a leading provider of comprehensive recall management services to manufacturers, distributors and retailers of pharmaceutical and medical device products. Our significant investment in technology and product development coupled with years of experience in recall management; ensures a reliable, complete solution.

Returns Online and its clients rely on precise and very timely information collection. As such, Returns Online has invested millions of dollars in creating the technology platform and facilities infrastructure to provide this critical data as quickly and accurately as possible. Because of our founders' many years of experience in the pharmaceutical recall industry and the considerable research completed to create our state-of-the-art infrastructure, we are qualified to comment on the June 18, 2002 proposed bar code labeling requirements cited above.

General Comment
Returns Online, Inc., commends and supports the development of a regulation on bar code labeling for human drug products and medical devices for the following reasons:

The FDA and recalling firms, as well as the general public, rely on accurate information capture in the recall retrieval process to properly measure the ongoing effectiveness of the recall program. The quantity of products (both expected and received) as collected during the recall, are vital to the decision of continuing or closing a recall event. If a recall is "closed" prematurely due to inaccurate or untimely information, product left in the marketplace may pose a serious health risk to the general public.

In addition, technology can be adapted to further prevent the distribution of recalled product once an event has been initiated. When product is scanned for distribution, the system could alert the operator that this particular lot of product has been recalled and should not be distributed. This technology also creates efficiencies in identifying and separating recalled product from non-recalled inventory at all parties within the healthcare supply chain.

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Therefore, we fully support measures to improving both the accuracy and efficiency of collecting critical product data. As such, we believe that regulation should extend present bar code labeling requirements to the following parameters:

1. Bar code content for all pharmaceutical products (including OTC) should include NDC, lot number and expiration date as these are the major elements in the identification and segregation of recalled product. Currently, product is received, identified and counted by scanning NDC numbers (if available) and manually entering lot numbers. If machine-readable technology were utilized, it would dramatically reduce human errors caused by manual data entry mistakes (keyboard mis-strokes) or visual misinterpretations.

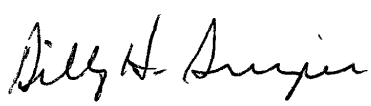
2. Bar code labeling requirements should expand to various medical devices. However, Returns Online is not qualified to provide comments on the exact scope of this proposal until further research is completed. At a minimum, we believe that any medical device that poses a potential serious health risk if recalled, should be required to have a standard bar code label on the packaging to identify the product, lot number and expiration date.

Conclusion

There are numerous, far-reaching benefits to expanding current bar code labeling requirements for pharmaceuticals and medical devices. As it pertains to safety recall management specifically, bar code labeling lot numbers and expiration dates enhances the accuracy and time efficiencies of collecting data. In turn, this provides the FDA and recalling firm the vital information necessary to monitor and assess the effectiveness of a recall event. Additionally, automation can improve the identification and segregation of recalled product to prevent further distribution; safeguarding the public against the dangers of receiving and using recalled product.

We welcome the opportunity to comment further on this notice, and if appropriate, meet with you to discuss these issues.

Sincerely,



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Executive Vice President
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returns online

Returns Online, Inc.
The National Returns Center™
14108 Lochridge Industrial Blvd.
Covington, GA 30014

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